

Ondansetron (Zofran®)

This sheet is about exposure to ondansetron in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is Ondansetron?

Ondansetron is a medication used to treat nausea and vomiting following surgery, chemotherapy, or radiation therapy. Ondansetron has also been prescribed during pregnancy to help with symptoms of nausea and vomiting in pregnancy (NVP). NVP is also referred to as “morning sickness”. Ondansetron is taken by mouth, infused into a vein (by IV) or given by injection into a muscle (IM). Ondansetron is sold under the brand name Zofran®.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

What can I do to help control my nausea and vomiting?

MotherToBaby has a fact sheet on nausea in pregnancy at: <https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/>. Also, talk to your healthcare provider about which NVP treatments are right for you.

I take ondansetron. Can it make it harder for me to get pregnant?

There are no human studies that have looked to see if ondansetron could make it harder for a person to get pregnant. Studies in animals did not find that ondansetron would affect the ability to get pregnant.

Does taking ondansetron increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Based on the studies reviewed, ondansetron is unlikely to increase the chance of miscarriage.

Does taking ondansetron increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Most studies have not reported an increased chance for birth defects among thousands of people who used ondansetron in pregnancy. A few studies reported a very small (less than 1%) increase in the chance for a cleft palate (an opening in the roof of the mouth that can be repaired with surgery) or a heart defect. Other factors that could affect the pregnancies exposed to ondansetron, such as the medical condition could explain these results.

Does taking ondansetron in pregnancy increase the chance of other pregnancy related problems?

Studies did not find a higher chance of pregnancy loss, preterm delivery (delivery before 37 weeks of pregnancy), or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) when ondansetron was used during pregnancy.

When taken at higher doses, there have been reports that ondansetron use might cause a heart rhythm problem (called QT interval prolongation) in the person taking ondansetron. In severe cases, this could become an abnormal heart rhythm known as Torsades de Pointes. If you are taking ondansetron, talk to your healthcare provider about your dose and how to watch for changes in your heart rhythm.

Does taking ondansetron in pregnancy affect future behavior or learning for the child?

One study looked at 78 infants who were exposed to ondansetron at any time during pregnancy. When examined between 7 days to 2 months of age, there were no unusual behaviors reported. A single follow-up survey for about 25 of these children was sent in by the parents. The children were between 1½ years to 5½ years old. The survey asked about behavior. The surveys did not report behavior differences in these children compared to children who were not exposed to ondansetron during pregnancy. There are no other studies looking at the use of ondansetron in pregnancy and long-term effects for the baby.

Breastfeeding while taking ondansetron:

There have been no studies in humans looking at the use of ondansetron during breastfeeding. Studies in animals suggest that ondansetron enters breast milk, but the effects of ondansetron on a breastfeeding infant are not known. If ondansetron use is necessary, it is not usually a reason to stop breastfeeding. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a male takes ondansetron, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Studies have not been done to see if ondansetron could affect male fertility or increase the chance of birth defects in humans. Animal studies have not shown any effect on male fertility. In general, exposures that fathers and sperm donor have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

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